

## Remarks

Claims 1 to 25, 28 to 33 and 35 to 40 are pending in the current application. Claim 24 has been amended. Claim 41 is new. Support can be found, e.g., on page 9, in the paragraph starting on line 32 (compare claim 1).

### **35 USC §102(b) rejection**

On page 3, the Office continued to reject claim 24 under 35 USC 102(b) as being anticipated by Greenberg (US Patent No. 5,569,458 hereafter “Greenberg”). Greenberg is said to disclose a dietary supplement comprising bromelain, papain, trypsin, and chymotrypsin, vitamins, selenium containing substances, citrus bioflavonoid complex, amino acids, and mucopolysaccharides. With a reference to col. 5, lines 26 to 28, Greenberg is also said to disclose a composition that strengthens the immune system.

Claim 24 has been further amended to highlight the difference between the food product and the nutritional formula of Greenberg.

The amendments are based on page 2, lines 21 to 26 of the application as filed.

Greenberg’s composition is encapsulated and thus not a food product as presently claimed. Greenberg, missing one of the limitations of the presently claimed invention, thus does not anticipate the claimed invention.

### **35 USC §103(a) rejection**

Starting on page 3, the Office repeats its rejected claims 1-23, 25, 28-33 and 35-40 under 35 USC 103(a) in view of Greenberg, Murray, Manthey et al., Rayman, Vetvicka et al., Ochao et al., Birt et al. and Jensen et al.. The Office does not further discuss this rejection. The Office is directed to the last response for the argument presented and notes that the teaching of Murray are similar to that of Sharid et al (below). Thus, the

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arguments present below also apply to the combination of Greenberg and Murray.

Starting on page 4, the Office rejected claims 1-25, 28-33 and 33 to 40 under 35 U.S.C. 103(a) as being unpatentable over Greenberg (US Patent No. 5, 569,458) in view of Shahid et al. (J Assoc Physicians India, 2002, Vol. 50, p.527-531) and further in view of Rayman, M. P. (The Lancet, 2000, Vol. 356, p. 233-241) and Vetvicka et al. (JANA, 2002, Vol. 5, No.2, p.5-9) and Ochao et al. (Journal of Parenteral & Enteral Nutrition, 2001, Vol. 25, No. 1, p.23-29) and Birt et al. (Pharmacology & Therapeutics, 2001, Vol. 90, p.157-177) and Jensen et al. (J. Nutr., 1999, Vol. 129, p.1355-1360), and Hughes et al. (The Journal of infectious diseases, 2000, Vol. 182, Suppl. 1, S11-S15).

The Office continues to acknowledge that Greenberg **does not teach**:

- one or more **proteases** having a **total concentration of 20% to 60% by weight** of active constituents in the composition, and
- flavonoids having a total concentration of 10% to 50% by weight of active constituents as recited in claim 1.

The Office also acknowledges that Greenberg does not teach specific embodiments that are claimed in several dependent claims, such as that the carotinoid is lycopene, the amino acid is L-arginine etc.

The Office states:

“However, since the specific activity of the enzymes are taught by Greenberg et al., a person of ordinary skill in the art at the time the invention was made, knowing the specific activities of the enzymes, would have been capable of calculating the amount of enzyme (in %) to be added to the formulation based on the total weight according to the teachings of Greenberg et al.” (*emphasis added*).

(Note: With regard to the “specific activity” of the digestive enzymes, applicants note that Greenberg teaches that the digestive enzymes are included into his vitamin and

mineral formulation to remedy the common dietary supplement problem of low absorbability of nutrients (abstract, col. 4, lines 45 to 48)).

The Office follows the above statement with a discussion of the teachings of the seven secondary references, in particular Sharid et al. which discloses the oral administration of PHLOGENZYM (Bromalin (90 mg), Trypsin (48 mg), rutin (100mg)), which comprises high amounts of proteases, which according to the Office's calculation, amounts to 57.9%. Applicants note that there are no vitamins and minerals in Sharid et al.'s PHLOGENZYM.

The Office concludes in view of these teachings that:

"a person of ordinary skill in the art at the time the invention was made, knowing the specific activities of the enzymes, would have been motivated to optimize the amount of enzymes . . . as taught by Greenberg according to teachings of Shahid et al. with a reasonable expectation of success in order to provide a composition with an improved immune strengthening properties, because Shahid et al. teach oral administration of a proteolytic enzymes formulation (bromelain, trypsin, and rutin, containing 57.9% total enzyme concentration and % 42.1 total flavonoid concentration) regulates the immune function." (*emphasis added*)

Applicants disagree.

Greenberg claim is directed at a supplement formulation in which

"the at least one herb, at least one digestive enzyme, and at least one pH balancing substance, together making up no more than approximately 10% of the weight of the nutrition formulation." (*emphasis added*, col. 6, lines 53 to 56)

The reasons for the upper limit of 10% become clear when reading the remainder of Greenberg's disclosure. Greenberg includes goldenseal specifically into his vitamin and mineral formulation to prevent the digestive enzymes from "eating up" the other

**nutrients** (Abstract, col. 3, lines 59 to 66). As noted above, with the inclusion of the digestive enzymes, Greenberg seeks to remedy a common dietary supplement problem of low absorbability of the nutrients (col. 4, lines 45 to 48). Greenberg also notes, that although the addition of enzymes may not increase its long-term marketability [due to shorter **shelf life**], the formula's increased absorbability of its nutrients greatly increases the effectivity and performance of his invention (paragraph bridging col. 4 and 5).

MPEP § 2143.03(VI) states that "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." Accordingly, where cited art teaches away from a claimed feature, the cited art is not available for the purposes of an obviousness rejection. In the instant case, Greenberg not only fails to teach or suggest that the proteases have a total concentration of 20% to 60%, but further teaches away from those concentrations (see above). As a result, one of ordinary skill in the art would not modify Greenberg's vitamin and mineral formulation to incorporate the high concentrations of proteases taught Sharid et al. to arrive at the claimed invention. Accordingly, applicants respectfully submit that the rejection is improper and request that the rejection be withdrawn.

Greensberg's teachings of the effects of the enzymes on the nutrients in his vitamin and mineral formulation also strongly suggest, that increasing the enzyme concentration in Greenberg's formulation would render his formulation unsatisfactory for its intended purpose, namely to provide a vitamin and mineral formulation. It is well established that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (MPEP 2143.01).

With respect to the food product of claim 24 no separate obviousness analysis was

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presented to support a *prima facie* case of obviousness.

Applicants have clearly shown that no *prima facie* case of obvious has been established with regard to claims 1 to 23, 25, 28 to 33 and 35 to 40 and that claim 24 is not anticipated by Greenberg. In view of this, an early issuance of a notice of allowance is respectfully requested.

If there remain any outstanding issues, the Office is urged to call the undersigned at (301) 657-1282 (direct).

No fees in addition to the fees submitted herewith are believed to be due. However, the Commissioner is authorized to charge any fee deficiencies or overpayment to the undersign's deposit account 50-3135.

Respectfully submitted,

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